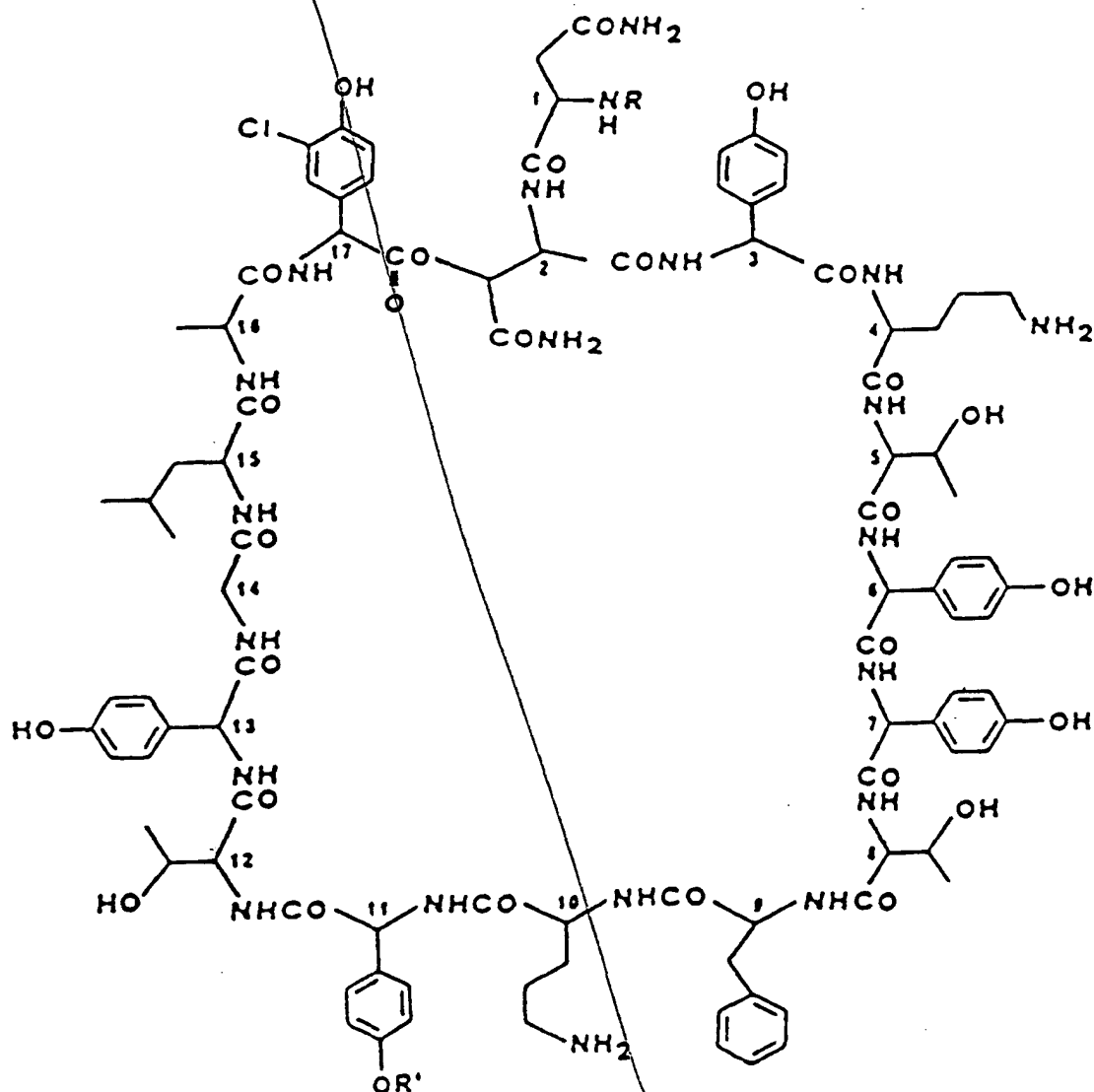


## CLAIMS

1. Pharmaceutical formulation for intravenous administration which comprises ramoplanin or a member of the ramoplanin family of formula I



FORMULA I

Wherein:

R represents  $\text{-CO-CH=CH-CH=CH-CH}_2\text{-CH}_2\text{-CH}_3$ ,  
 $\text{-CO-CH=CH-CH=CH-CH}_2\text{-CH(CH}_3)_2$ ,  
 5  $\text{-CO-CH=CH-CH=CH-CH}_2\text{-CH}_2\text{-CH(CH}_3)_2$ ,  
 $\text{-CO-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_3$ ,  
 $\text{-CO-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH(CH}_3)_2$  or  
 $\text{-CO-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH(CH}_3)_2$

10 R' represents  $\alpha$ -D-mannopyranosyl or 2-O- $\alpha$ -D-mannopyranosyl- $\alpha$ -D-mannopyranosyl, or

R' represents 2,3-O-di[ $\alpha$ -D-mannopyranosyl]-D-mannopyranosyl and R represents  $\text{-CO-CH=CH-CH=CH-CH}_2\text{-CH(CH}_3)_2$ ,  
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a pharmaceutically acceptable acid addition salt thereof, or a mixture thereof in any proportion,

20 in admixture with an amount of fat emulsion product for intravenous administration wherein the concentration of the oil phase is at least 0.2% (weight/vol).

25 2. A formulation according to claim 1 wherein the fat emulsion product comprises an oil phase, an emulsifier and an additive as an osmotic agent.

3. A formulation according to claim 2 wherein the fat emulsion product comprises as an oil phase vegetal oils such as soybean, cottonseed oil, safflower oil or a mixture thereof, an emulsifier based on phospholipids, preferably from egg source such as egg lecithin, soybean lecithin or a mixture thereof, and an

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additive as osmotic agent such as sorbitol, glycerol, xylitol or a mixture thereof.

4. A formulation according to claim 3 wherein the oil phase is in a range from 0.2 to 40 percent (weight/vol), preferably, from 4 to 25 percent, more preferably, from 8 to 18 percent and, most preferably, from 8 to 10 percent of the final formulation.

5. A formulation according to any of claims 1 to 4 wherein the fat emulsion product employed for the preparation of said formulation contains from 2 to 40 percent, (weight/vol), preferably, from 5 to 25 percent, more preferably from 7 to 20 percent of oil phase, from 0.2 to 5 percent, (weight/vol), preferably, from 0.6 to 2 percent, more preferably, from 0.5 to 1.5 percent of emulsifier and an additive in an amount suitable to control osmolarity, preferably in a range from 1.5 to 5 percent (weight/vol), preferably from 2 to 3 percent.

6. A formulation according to any of claims 1 to 5 wherein the oil phase contains long chain fatty acids in the form of triglycerides in the following proportions by weight:

25	linoleic acid	40-70%
	oleic acid	15-30%
	palmitic acid	5-15%
	linoleic acid	3-12%
	stearic acid	2-6%

7. A formulation according to any claims 1 to 6 wherein the fat emulsion product employed for the preparation of said formulation comprises a composition selected from those reported in the following tables:

	Fat emulsion product 1	Fat emulsion product 2	Fat emulsion product 3
Soybean oil (w/vol)	10%	20%	5%
Safflower oil (w/vol)	--	--	5%
Egg yolk phospholipids (w/vol)	1.2%	1.2%	1.2%
Glycerol (w/vol)	2.25%	2.25%	2.5%
Fatty acids composition of vegetable oils (w/vol)			
Linoleic acid	50%	50%	65.8%
Oleic acid	26%	26%	17.7%
Palmitic acid	10%	10%	8.8%
Linolenic acid	9%	9%	4.2%
Stearic acid	3.5%	3.5%	3.4%
Osmolarity (mOsm/L)	260	268	276
Approximate pH	8	8	8
Fat particle size ( $\mu\text{m}$ )	0.5	0.5	0.4
Caloric value (cal/ml)	1.1	2.0	1.1
Size (ml)	50, 100	50, 100	25, 50
	250 or	250 or	100, 200
	500	500	Or 500
	Fat emulsion product 4	Fat emulsion product 5	Fat emulsion product 6
Soybean oil (w/vol)	10%	10%	20%
Safflower oil (w/vol)	10%	--	--
Egg yolk phospholipids (w/vol)	1.2%	1.2%	1.2%
Glycerol (w/vol)	2.5%	2.5%	2.5%

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Fatty acids composition of vegetable oil (w/vol)			
Linoleic acid	65.8%	54.5%	54.5%
Oleic acid	17.7%	22.4%	22.4%
Palmitic acid	8.8%	10.5%	10.5%
Linolenic acid	4.2%	8.3%	8.3%
Stearic acid	3.4%	4.2%	4.2%
Osmolarity (mOsm/L)	258	284	292
Approximate pH	8.3	8.3	8.3
Fat particle size ( $\mu$ m)	0.4	0.4	0.4
Caloric value (cal/ml)	2.0	1.1	2.0
Size (ml)	25, 50	100, 200	200 or
	200 or	Or 500	550
	500		

and water for injection q.s. to 100%.

8. A formulation according of claims 6 or 7 wherein soybean oil and/or cottonseed oil and/or safflower oil are totally or partially replaced by a mixture of long chain fatty acids in the form of triglycerides to form a composition wherein said fatty acids are present in the respective proportions indicated in said claims and, optionally part of the above oils or long chain fatty acids is substituted by medium chain (C<sub>6</sub>-C<sub>12</sub>) triglycerides.

9. A formulation according to any of claims 1 to 8 wherein the concentration of the oil phase is between 4 and 25% (weight/vol), preferably, between 8 and 18%, more perferably between 8 and 10% of the final formulation.

10. A formulation according to claim 9 wherein the concentration of the oil phase is between 8 and 10% (w/vol) of the final formulation.

5 11. A formulation according to any one of claims 1 to 10 wherein ramoplanin is present at a concentration between 1 and 20 mg/ml, preferably from 1.5 to 15 mg/ml, most preferably, from about 3 to about 5 mg/ml.

12. A formulation according to any of claims 1 to 11 wherein the pH of the final formulation is lower than 8, preferably, lower than 7.

15 13. A formulation according to any of claims 1 to 10 wherein the pH of the final formulation is between 4 and 6.5.

20 14. A formulation according to any one of claims 1 to 13 for treatment of infections caused by agents that are susceptible to ramoplanin or an antibiotic of the ramoplanin family.

25 15. A formulation according to any one of claims 1 to 13 for the treatment of serious Gram ~~positive~~ infections such as bacteremia, endocarditis or pneumonia.

30 16. A formulation according to any one of claims 1 to 13 for the treatment of severe infections caused by Gram positive drug-resistant or multiresistant microorganisms such as coagulase positive and negative staphylococci, penicillin-resistant streptococci or glycopeptide resistant enterococci.

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17. A formulation according to any one of claims 1 to 16 wherein ramoplanin factor A<sub>2</sub> is present in an amount of at least 75%.

18. A pharmaceutical composition which consists of a ready to use dosage form or of a kit comprising separate packagings or containers containing ramoplanin or a member of ramoplanin family and the fat emulsion product for constitution of a formulation according to any of claims 1 to 17.

19. A kit according to claim 18 which consists of vials or similar containers containing the dose of lyophilised sterile antibiotic, ampuls containing water for injection in amount sufficient to dissolve the antibiotic and bottles containing sterile fat emulsion product in amount appropriate for constituting the desired i.v. formulation.

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